Guidance for the New Oral Fluoroquinolone Contract

Department of Defense Pharmacoeconomic Center
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Effective Date: 15 January 2004 (Contract will be in effect for one year with an option to extend the terms of the contract for 4 additional one-year periods).

Selected Products: Gatifloxacin 200 mg and 400 mg Tablets, Bristol Myers Squibb Company

Formulary Guidance:

Table 1: Summary of the Formulary Status of Oral Fluoroquinolones at Military Treatment Facilities (MTFs)

MTFs must have on formulary:	MTFs may have on formulary:
All strengths of gatifloxacin oral tablets	Additional oral fluoroquinolones based on local susceptibility patterns

- **Gatifloxacin**: A joint DoD/VA open class contract was awarded to gatifloxacin for addition to the Basic Core Formulary as a "workhorse" fluoroquinolone for the indications of Community Acquired Pneumonia (CAP) and Acute Sinusitis**.** All strengths of oral gatifloxacin tablets must be on formulary at all MTFs. This drug class will remain "open" on the BCF, which means that MTFs are permitted to add additional products within the drug class on their MTF formularies.
- **Additional Oral Fluoroquinolones on MTF Formularies**: MTFs are allowed to have oral fluoroquinolones in addition to gatifloxacin on their formulary based on local susceptibility patterns. MTFs are encouraged to have ciprofloxacin as a second oral fluoroquinolone on formulary because the complementary clinical profiles of gatifloxacin and ciprofloxacin will cover the majority of infections requiring fluoroquinolone therapy.
- **TMOP and Retail Network Pharmacies**: The contract does not affect the availability of oral fluoroquinolones at the TRICARE Mail Order Pharmacy (TMOP) or retail network pharmacies. All oral fluoroquinolones are currently available at the TMOP and retail network pharmacies. The contract price for gatifloxacin will apply at the TMOP.
- **Injectable and Other Dosage Forms**: This contract only covers oral tablet dosage forms.

Prescribing Guidance for Prescriptions Filled at MTFs:

- **Background**: Citing the 6 May 03 minutes, "The Pharmacy and Therapeutics Executive Council reviewed the most current clinical data including efficacy, coverage and safety/tolerability. The Council unanimously voted to authorize a procurement strategy that could include up to a joint DoD/VA open class contracting strategy competing moxifloxacin, gatifloxacin, and levofloxacin as a "workhorse" fluoroquinolone for the indications of Community Acquired Pneumonia (CAP) and Acute Sinusitis."
- **National Guidelines for the Treatment of Sinusitis and CAP**: The March 2001 CDC position paper on appropriate antibiotic use for acute sinusitis in adults states that most cases of sinusitis do not require antibiotic treatment. The position paper recommends patients with severe or persistent moderate symptoms and specific findings of bacterial sinusitis should be treated with narrow-spectrum antibiotics as first-line agents, therefore broader spectrum antibiotics, like the fluoroquinolones, should be reserved for second-line therapy. The 2003 Infectious Disease Society of America (IDSA) CAP Guidelines recommend use of erythromycin, azithromycin, clarithromycin, and doxycycline as initial antibiotic treatment in patients with no recent antibiotic use and no comorbitidities. In patients recently treated with other antibiotics or with comorbidities a fluoroquinolone (gatifloxacin, levofloxacin, or moxifloxacin) may be appropriate. The selection of gatifloxacin as a "workhorse" fluoroquinolone for sinusitis or CAP does not mean that the DoD P&T Executive Council advocates indiscriminate use of gatifloxacin for all cases of sinusitis and CAP. Gatifloxacin should be used only when clinically appropriate.
- **Fluoroquinolone Treatment of CAP and Sinusitis:** DoD and VA clinical reviews, as well as Infectious Disease Consultants from each service, concluded that gatifloxacin, levofloxacin and moxifloxacin could be used interchangeably to treat community acquired pneumonia (CAP) or sinusitis when a fluoroquinolone is

clinically indicated. The contract requires that gatifloxacin be used as the first-line oral fluoroquinolone for all new patients with CAP or sinusitis that have a clinical need for an oral fluoroquinolone, unless there is a medical reason to use a different oral fluoroquinolone. If a patient with CAP or sinusitis has a medical necessity to use an oral fluoroquinolone other than gatifloxacin, a second MTF formulary oral fluoroquinolone can be prescribed, or a non-formulary oral fluoroquinolone can be provided through the command-approved non-formulary procedures for documentation of medical necessity. Examples of medical necessity include, but are not limited to:

- Documented gatifloxacin antibiotic resistance in your geographic area
- Previous treatment failure to gatifloxacin
- Taking a drug with known drug interactions with gatifloxacin
- Unacceptable adverse effects with gatifloxacin
  - Special note: Diabetic patients receiving oral hypoglycemic agents or insulin and a fluoroquinolone appear to be at increased risk for dysglycemic events, although these events are rare. Dysglycemic events have been reported with all fluoroquinolones. They have been reported more frequently with gatifloxacin, however the true difference in incidence is unknown. In the diabetic population all fluoroquinolones should be used with caution.

The contract does not mandate that patients currently receiving a course of oral fluoroquinolone therapy be switched to gatifloxacin.

- **Fluoroquinolone Treatment of Conditions Other than CAP and Sinusitis:** Although the contract does not require the use of gatifloxacin as initial therapy in patients with conditions other than CAP or sinusitis, gatifloxacin, the most cost effective agent, should be used when clinically appropriate.

Contract Prices:

Table 2. Gatifloxacin (Tequin®) Product Information

Strength	Dosage Form	NDC	Package Size	Price per Package	Price per Tablet
200mg	Tablet	00015-1117-50	30	$40.50	$1.35
400 mg	Tablet	00015-1177-60	50	$67.50	$1.35
200 mg	Tablet	00015-1117-80	100	$135.00	$1.35
400 mg	Tablet	00015-1177-80	100	$135.00	$1.35
400 mg	Tablet	00015-1177-21	3 Teq-paqs (5 tabs ea)	$20.25	$1.35

Economic Impact of the Contract in DoD:

The $1.35 price for gatifloxacin is 33% less than the $2.01 per tablet that MTFs have been paying for gatifloxacin (which was based on a blanket purchase agreement that specified that levofloxacin would be the only fluoroquinolone on the Basic Core Formulary). The levofloxacin BPA expired December 31, 2003. We do not have definitive price information at this time, but the price of levofloxacin is expected to increase to the FSS price of $5.26 per tablet on 31 January 2004. Table 3 shows the range of potential cost savings that can result from using gatifloxacin instead of levofloxacin.

Table 3. Potential Cost Savings with Gatifloxacin Contract

Drug (Oral formulations only)	Cost/day	Cost savings/day with gatifloxacin	Cost/ 10-day course of therapy	Cost savings/10-day course of therapy with gatifloxacin
Levofloxacin	$2.01 to $5.26/day	$0.65 to $3.91/day	$20.00 to $52.60/ 10 day course	$6.50 to $39.10/ 10 day course
Gatifloxacin	$1.35/day		$13.50/ 10 day course	
If an MTF dispensed 10,000 doses of levofloxacin annually, using gatifloxacin instead of levofloxacin would yield a cost savings between $6,500 and $39,000.				
DoD MTFs dispensed 3.1 Million doses of levofloxacin and gatifloxacin in FY03. If MTFs used only gatifloxacin, the cost savings would be approximately $2.1 million based on 2003 prices, or as much as $11.6 million based on projected prices for 2004.				

PEC Recommendation:

The DoD P&T Executive Council held an interim meeting by email on 8 January 2004 and voted to remove levofloxacin from the Basic Core Formulary. Given the anticipated levofloxacin price increase to $5.26 per tablet, the PEC strongly recommends that MTFs remove levofloxacin from their formularies. Levofloxacin should only be used in cases of medical necessity when a more cost effective fluoroquinolone will not meet patients' clinical needs. Additionally, the PEC recommends ciprofloxacin as the second fluoroquinolone for those MTFs that find it necessary to have a second fluoroquinolone on their formularies.

MTF fluoroquinolone expenditures have risen steadily in recent years. Due to the large price increase that is projected for levofloxacin, MTFs must act quickly to maximize the cost saving potential of the gatifloxacin contract. Gatifloxacin became available at the contract price of $1.35 per tablet on 1 January 2004, but if the levofloxacin price increases to $5.26, MTFs will need to move 83% of their new fluoroquinolone prescriptions to gatifloxacin to "break even" with the historical $2.01 cost per dose that existed under the levofloxacin BPA. The huge price increase for levofloxacin will cause financial harm for an MTF unless it achieves 83% contract compliance within two months of the contract start date of 15 January 2004 (based on FY 03 utilization rates).

Points of Contact:

CDR Ted Briski, MSC, USN, Contracting Coordinator, DoD Pharmacoeconomic Center, Fort Sam Houston, TX
(210) 295-2771 e-mail: Ted.Briski@amedd.army.mil

CDR Denise Graham, MSC, USN, DoD Pharmacoeconomic Center, Fort Sam Houston, TX
(210) 295-2791 e-mail: Denise.Graham@amedd.army.mil

Mr. David Bretzke, R.Ph., DoD Pharmacoeconomic Center, Fort Sam Houston, TX
(210) 295-2782 e-mail: David.Bretzke@amedd.army.mil